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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WILLIAM A. KNAUS and RICHARD D. MARKS

Appeal 2009-0552
Application 09/822,261
Technology Center 3600

Decided:[1] May 1, 2009

Before, MURRIEL E. CRAWFORD, ANTON W. FETTING and JOSEPH A. FISCHETTI, *Administrative Patent Judges*.

FISCHETTI, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] The two month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

STATEMENT OF THE CASE

Appellants seek our review under 35 U.S.C. § 134 of the Examiner's final rejection of claims 1-29, 46-62, 64-71 and 73-75. We have jurisdiction under 35 U.S.C. § 6(b). (2002).

SUMMARY OF DECISION

We AFFIRM.

THE INVENTION

Appellants claim a system and method for individualized control and management of medical records. In particular, the invention relates to methods in which the creation, control and management of medical records are secure and certified as accurate, having the attribute of non-repudiation. (Specification 1:8-10)

Claim 1 reproduced below, is representative of the subject matter on appeal.

A broad-band, computer-based networked system comprising:

a collection of patient-based electronic medical records of a plurality of persons, at least one of which is encrypted or secured when collected, accessed, inputted, viewed, integrated or transmitted, wherein:
the medical records are obtained and electronically compiled from a plurality of sources;

one or more medical records of the collection possess a characteristic of non-repudiation such that medical information contained within said medical records is verified as to accuracy and certified for accuracy;
the medical record of a person is transmitted in whole or in part only to that person and others authorized by that person;

each medical record is supplemented with additional information; and additional medical records for additional persons are added to the collection;
a secure access for allowing each person to access only their own medical

record; and at least another secure access for allowing said others authorized to access only that person's medical record.

THE REJECTION

The Examiner relies upon the following as evidence of unpatentability:

Shear	4,827,508	May 2, 1989
Shepard	6,026,363	Feb. 15, 2000
Malik	US 2001/0037219 A1	Nov. 2001
Snowden	US 2002/0026332 A1	Feb. 28, 2002

Baker, D.B. "PCASSO: A Model for Safe Use of the Internet in Healthcare" Journal of AHIMA, March 2000, pp. 33-36

The following rejections are before us for review.

The Examiner rejected claims 1-11, 18-26, 29, 46-47 and 51-75 under 35 U.S.C. § 103(a) over Snowden in view of Shepard.

The Examiner rejected claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Snowden in view of Shepard and further in view of Baker.

The Examiner rejected claims 13-15, 27-28, and 48-50 under 35 U.S.C. § 103(a) as being unpatentable over Snowden in view of Shepard and further in view of Malik.

The Examiner rejected claims 16-17 under 35 U.S.C. § 103(a) as being unpatentable over Snowden in view of Shepard and further in view of Shear.

ISSUE

Have Appellants shown that the Examiner erred in rejecting claims 1-11, 18-26, 29, 46-47 and 51-75 on appeal as being unpatentable under 35 U.S.C. § 103(a) over Snowden in view of Shepard on the grounds that a person with ordinary skill in the art would understand that Shepard discloses "certification" and "non-repudiation" of the records created and stored against a patient's file?

Have Appellants shown the Knaus and Marks Declarations to be sufficient in character and weight as to establish reduction to practice prior to the effective dates of the Snowden and Malik references?

Have Appellants shown that the Examiner erred in rejecting claim 20 on appeal as being unpatentable under 35 U.S.C. § 103(a) over Snowden in view of Shepard on the grounds that a person with ordinary skill in the art would understand that Shepard discloses at least one medical record is better than exists at a source site from which the medical record was obtained in that the writer who vets the record, e.g., decodes key word and phrases does create a record which is better than that verbalized by the healthcare worker because it is no longer in encoded form and has benefited from a further

vetting process, such as, being run through word processing, e.g., cleared for spelling errors, etc.

FINDINGS OF FACT

We find the following facts by a preponderance of the evidence:

1. The Examiner found that "… Snowden does not expressly disclose one or more medical records of the collection possess a characteristic of non-repudiation such that medical information contained within said medical records is verified as to accuracy and certified for accuracy." (Answer 4.)

2. The Examiner further found that "Shepard discloses one or more medical records of the collection possess a characteristic of non-repudiation such that medical information contained within said medical records is verified as to accuracy and certified for accuracy (col. 13, line 54 - col. 14, line 9 of Shepard)." (Answer 4).

3. The Examiner accordingly found "…it would have been obvious to a person of ordinary skill in the art to combine the features of Shepard within Snowden. The motivation for doing so would have been to provide accurate and complete patient documentation to meet legal, insurance and third party medical service provider requirements…. (Answer 5)

4. Shepard discloses:

> When the transcriber has prepared the patient final report, the transcriber or writer then compares the final report to the encoded indicia recorded on the preprinted form, which is depicted by Box 44, to ensure that the final report is accurate.

> The final report is then prepared by an imaging device and may be in the form of a patient report to be filed in a patient's history file or in the form of a letter to be sent to a third party as depicted by Box 46.
>
> The final report or letter, as depicted by Box 46, is then reviewed and signed by the healthcare professional who performed the examination of the patient. If the medical history documentation system is a manual system using a transcriber as described above, the healthcare professional would review all patient reports at the end of the day.
>
> If the medical history documentation system is a computerized system, e.g., a scanner is used to scan the preprinted form and scan the predetermined encoded indicia as an input to the computer, the healthcare professional can be provided a final report or letter for review and sign upon completion of the physical examination of the patient as depicted by Box 50. (Shepard, col. 13, l. 54 - col. 14, l. 9).

5. The Specification describes the limitation "non-repudiation" in terms of :

> [m]edical records that are verified as accurate attain the aspect of non-repudiation (i.e. that the accuracy and correctness of the information is as good or better than exists at the source sites from which the records were obtained), and may for all purposes be relied upon. As such, non-repudiated records may therefore be primary for future treatment or diagnoses. (Specification 17:14-18).

6. The Specification describes "certification" as having three modes as set forth below as follows:

> [a.] Certification levels may refer to standards of verification such as, for example, "initial" being self-certification wherein the member certifies that the record is correct, "basic" whereby the system provider certifies that the record is complete for all information gathered, "enhanced" whereby the system provider certifies that the information is complete and correct, or comprehensive" whereby the system provider certifies that the information provides a complete, accurate and verifiable medical record. Subdivisions of each level such as, for example, grades may also be utilized (e.g. Basic-l, -2, -3, etc.). (Specification 15:22-29).
>
> [b.] Alternatively, the certification level may also provide an indication of the level of completeness of the record. For example, an initial level of certification may be limited to annual medical examinations. Data associated with such an examination is input into the system and each input would include an indication of source which may be verified by the system provider according to provider-defined criteria. A basic certification level may include information necessary for a initial certification level, plus additional information relating to hospital out-patient procedures performed along with source and source verification. An enhanced level of certification may include basic information plus further in-patient information. A comprehensive level may include enhanced information plus correlation information such as, for example, a

> review for completeness, vetting, a review for accuracy, and noting and/or linking of any discrepancies (e.g. drug allergies, disparate diagnoses, anomalies, and otherwise unexplained treatments and observations). (Specification 15:29-16:12).
>
> [c.] Certification may simply state that the record is correct in all material respects or that the record is internally consistent. Errors identified in medical records may be corrected (with appropriate annotation) or simply noted. Suggestions in the form of supplemental computerized evaluations or other helpful comments may be included with comprehensive certification as to possible diagnoses, possible treatment or health options, and the like. Thus, a part of each level of certification may be a verification that the information is exactly as it appears in the paper or other tangible or even electronic file of the original source, or possibly better. (Specification 16:12-19).

7. The Specification defines patient–based as "… the medical records of an individual are controlled and managed by that individual…." (Specification 13:4-6.)

8. The Specification describes vetting in the context of

> [f]urther information can be obtained from other sources (medical professionals and paraprofessionals, nurses, physicians), and all of the information subject to review and appraisal by clinically trained experts or record-experienced experts. Medical records that have been so reviewed are considered to have been vetted.

> Vetted medical records contain corrections and annotation information such as, for example, a review for accuracy and completeness noting and/or linking any errors or discrepancies (e.g. drug allergies, disparate diagnoses, anomalies, and otherwise unexplained treatments and observations). Vetting may be a part of a certification standard (e.g. comprehensive) or may simply be a statement that the record has been vetted and is correct in all material respects, is internally consistent and/or has been corrected. (Specification 20:17-26)

9. Snowden discloses a patient centered record system in that it allows "…patients to play a more active role in the management and maintenance of their health. (Snowden, ¶[0102]).

10. The Specification describes that "… vetting is performed by the patient, by the source from which the records were obtained, by the system provider, or by a combination thereof." (Specification 20:27-28.)

11. Snowden further discloses a patient centered record system in that:

> FIG. 1 shows a system in which medical information for a consumer is gathered from a variety of sources, a copy of which is stored in a database that is controlled and owned by the consumer. This database is automatically updated on a regular basis. The database information can then be transmitted by the consumer to doctors, hospitals, other healthcare providers, or insurance companies as desired by the consumer. (Snowden, ¶[0103])

12. The system in Shepard is primarily concerned with documentation of medical history using a recording apparatus to record information communicated by a healthcare person. (Shepard, col.1, ll. 20-23.)

13. Shepard discloses that a "…writer, who accompanies the healthcare professional, records in a predetermined format with a recording device, for example the writer Records On a Preprinted Form 38 (or on a computer input apparatus), the patient's medical information verbalized by the healthcare professional during the physical examination of a patient. (Shepard, col.13, ll. 5-10.)

14. Shepard further discloses that the writer, who accompanies the healthcare professional then prepares a patient final report using a "…known word processing system and hav[ing] templates of optional variable text segments which the transcriber would select or program, essentially decoding the key words and phrases to produce a final report." (Shepard, col.13, ll. 50-54.)

15. The Knaus Declaration Exhibit A discusses the involved system and method in the future tense stating, e.g., "My approach would use….; This would effectively eliminate…."; "they will also be able to devote time….; "Individuals therefore would be the main customers for this service." (Knaus Declaration, p.4).

16. The Knaus Declaration Exhibit A states using the future tense, "I can envision linking …."; It could monitor and direct…."(Knaus

Declaration, p.6).

17. The Knaus Declaration Exhibit A admits the information outlined is conceptual stating, "If we get through this conceptual phase…." (Knaus Declaration, p. 7).

18. The Knaus Declaration seeks to antedate the effective dates of each of Snowden, Malik, the Snowden Provisional and the Malik Provisional applications relied on by the Examiner alleging *inter alia*:

> Prior to December 6, 1999, we conceived and reduced to practice the systems and methods according to the claims of the instant patent application, at least to the extent that such systems and methods are disclosed in U.S. Patent Application No. 09/908,524 (Snowden), U.S. Provisional Application No. 60/169,065 (the Snowden Provisional), U.S. Patent Application No. 09/776,673 (Malik), and U.S. Provisional Applieation No. 60/60/200,091 (the Malik Provisional) (collectively the "Cited References"). Accordingly, Snowden, Malik, the Snowden Provisional and the Malik Provisional cannot be considered to be prior art to our claimed invention.
>
> (Knaus Declaration, p. 1).

19. The Knaus Declaration does not assert any facts which show diligence.

PRINCIPLES OF LAW

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). *See also KSR*, 127 S.Ct. at 1734 ("While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.").

ANALYSIS

We affirm the rejection of claims 1-29, 46-62, 64-71 and 73-75.

Appellants' arguments against each of independent claims 1, 20, 46 and 65 are based on perceived deficiencies of Shepard. Inasmuch as Appellants raise the same issues with respect to each of these claims, we discuss them together, addressing each of Appellants' arguments in turn.

Initially, we note that the Appellants argue the claims 1, 46, and 65 together as a group. Correspondingly, we select representative claim 1 to decide the appeal of these claims, remaining claims standing or falling with claim 1.

Group I: Claims 1-11, 18-26, 29, 46-47 and 51-75.

Preliminarily, we address the scope of the claims. Each of the independent claims requires non-repudiation and certification. Appellants

state that these claim elements are understood by those of ordinary skill in the art and thus "Appellant (*sic*) is not incorporating a definition from the specification, but merely demonstrating that the specification is consistent with the context and the plain meaning of this term in the claims." (Appeal Br. 8, 9). Having been alerted to the presence of such a definition, we thus use the definition provided by the Specification for these terms in our analysis. Accordingly we interpret non-repudiation as meaning that the accuracy and correctness of the information is as good or better than exists at the source sites from which the records were obtained (FF5) and certification to mean that the record is correct in all material respects or that the record is internally consistent (FF 6c).

Appellants maintain that "Shepard is not combinable with Snowden and would not lead one skilled in the art toward Appellants' invention. Appellants' claimed invention is directed to patient-based records. Shepard is directed to the conventional hospital-based or physician-office system, or, in other words, to an institutional source-centered record system, which leads one skilled in the art in exactly the wrong direction." (Appeal Br. 10)

We disagree with Appellants. First, we find that Snowden discloses a patient centered record system because in Snowden, patients play an active role in the management and maintenance of their health (FF 9) and further that medical information for a consumer is controlled and owned by the consumer (FF 11). This is congruent with Appellants' definition of patient-based (FF 7). Thus, we conclude that a system such as taught by Snowden

which explicitly discloses allowing a patient to play a more active role in the management of their health and allowing them to control and own their medical information is patient-based or centered.

Second, we find nothing in the disclosure of Shepard which would prohibit the medical records of a patient once entered and verified from being controlled and owned by that patient as taught by Snowden because Shepard is primarily concerned with the documentation of medical history communicated by a healthcare person into fixed form (FF 12). Since the Examiner has provided some articulated reasoning with some rational underpinning for why a person with ordinary skill in the art would modify Snowden to use the characteristic of non-repudiation of Shepard (FF 3), Appellants' argument is not persuasive as to error in the rejection.

Appellants next argue:

> The Shepard medical record management system is directed to physician- or a hospital- based records system.... Thus, Shepard's records would be verified as correct only by the health care professional who conducted the examination. This is not a patient-based record system as described in the instant application, but a conventional hospital-based record system for creating original medical records. (Appeal Br. 10).

That argument is not well taken because the Appellant is attacking the Shepard reference individually when the rejection is based on a combination of references to both Shepard and Snowden and Snowden is being used to teach the patient-based feature as discussed above. *See In re Keller*, 642

F.2d 413, 426 (CCPA 1981); *In re Young*, 403 F.2d 754, 757-58 (CCPA 1968).

Appellants next argue that

> [a]ll the instances noted in Shepard refer to verification of the patient's record by the physician or health care worker who is tasked by the source with creating the record in the first place. Shepard describes delegating the task of actually writing the medical record to another person employed by the source office or hospital, and yet who is not administering the care. The recorder is, for example, to be present in the room when the patient is being examined by the physician…. (Appeal Br. 10).

We disagree with Appellants because the Specification describes that vetting can be performed by any of the patient, the source from which the records were obtained, the system provider, or by a combination thereof (FF 10). Thus, the transcriber in Shepard who works for the provider meets the claim requirement.

Appellants further argue error in the Examiner's finding of accuracy in the asserted prior art because "… her analytical approach is devoid of logic, arbitrary and capricious, and a violation of MPEP § 706." (Appeal Br. 12). We disagree with Appellants.

The pertinent claim language recites: *one or more medical records of the collection possess a characteristic of non-repudiation such that medical information contained within said medical records is verified as to accuracy and certified for accuracy*. The Examiner found that "Shepard discloses one

or more medical records of the collection possess a characteristic of non-repudiation such that medical information contained within said medical records is verified as to accuracy and certified for accuracy (col. 13, line 54 - col. 14, line 9 of Shepard)." (FF 2). The cited to portion of Shepard discloses that "when the transcriber has prepared the patient final report, the transcriber or writer then compares the final report to the encoded indicia recorded on the preprinted form, which is depicted by Box 44, to ensure that the final report is *accurate* (emphasis added)." (FF 4). Thus, we agree with the Examiner, Shepard discloses verifying for accuracy.

Further, according to Appellants, certification may simply state that the record is correct in all material respects or that the record is internally consistent (FF 6c). We find that Shepard discloses that the final report or letter is reviewed and then signed by the healthcare professional who performed the examination of the patient (FF 4). As such, we conclude that Shepard discloses certification in that the act of reviewing the content of the report and subsequent signing certifies by the signature to its internal consistency.

In addition, Shepard discloses that if the medical history documentation system is a computerized system, a scanner is used to scan the preprinted form and scan the predetermined encoded indicia as an input to the computer (FF 4). The healthcare professional is then provided a final report or letter for review and sign upon completion of the physical examination (FF 4). The Specification defines a non-repudiation document

as one where the accuracy and correctness of the information *is as good or* better than exists at the source sites from which the records were obtained (FF 5). Since a scanner will copy the document having accuracy and correctness of at least as good as the original, it thus meets the claim requirement. In light of the breadth of the claim, the Appellants' argument is not persuasive as to error in the rejection.

Regarding the dependent claims which Appellants include as part of Group I, we also affirm the rejections of these dependent claims since Appellants have not challenged such with any reasonable specificity (*see In re Nielson*, 816 F.2d 1567, 1572, (Fed. Cir. 1987)).

Declaration Evidence:
Group II Claims 1-29, 46-62, 64-71 and 73-75;
Group III Claims 13-15, 27-28 and 48-50.

We are not persuaded by Appellants' showing of facts in the Knaus and Marks Declarations to be sufficient in character and weight as to establish reduction to practice prior to the effective dates of the Snowden and Malik references. Rather, we find that the evidence presented in Exhibit A appended to the Declarations at best shows conception in that it only discusses the system in the future tense as actions to be completed by the concept (FF 16,17). In fact, the Exhibit A even references itself as a conceptual phase (FF 18).

Moreover, the Knaus and Marks Declarations Exhibit A fail to assert any facts of due diligence from the alleged time of conception date and thus cannot support conception of the invention prior to the effective date of the

reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application.

Accordingly, we reject Appellants' assertion that the Knaus and Marks Declarations are effective to antedate the effective dates of the Snowden and Malik references and the rejections which rely on these references.

Group IV Claim (claim 20)

Appellants argue claim 20 separately, maintaining that "...information contained within Shepard's source medical records cannot be better than exists at the source from which the record was obtained. This is at least because the hospital, physician or health care worker is the source of the record." (Appeal Br. 11) Claim 20 recites: *medical records representing a plurality of persons, wherein the medical information of at least one medical record of the plurality has been vetted, such that the medical information of said at least one medical record is better than exists at a source site from which the medical record was obtained and thereby is not subject to repudiation.*

We disagree with Appellants' position here because we read the source site in Shepard as being the healthcare professional. As such, we find that the writer who vets the record, e.g., decodes key word and phrases (FF 13,14) does create a record which is better than that verbalized by the healthcare worker because it is no longer in encoded form and has benefited from a further vetting process, such as, being run through word processing,

e.g., cleared for spelling errors, etc. *See KSR Int'l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007) (In making the obviousness determination one "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ").

CONCLUSIONS OF LAW

We conclude the Appellants have not shown that the Examiner erred in rejecting claims 1-11, 18-26, 29, 46-47 and 51-75 under 35 U.S.C. § 103(a) over Snowden in view of Shepard.

We conclude the Appellants have not shown that the Examiner erred in rejecting claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Snowden in view of Shepard and further in view of Baker.

We conclude the Appellants have not shown that the Examiner erred in rejecting claims 13-15, 27-28, and 48-50 under 35 U.S.C. § 103(a) as being unpatentable over Snowden in view of Shepard and further in view of Malik.

We conclude the Appellants have not shown that the Examiner erred in rejecting claims 16-17 under 35 U.S.C. § 103(a) as being unpatentable over Snowden in view of Shepard and further in view of Shear.

DECISION

The decision of the Examiner to reject claims 1-11, 18-26, 29, 46-47 and 51-75 is AFFIRMED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED

JRG

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